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COMPLETED ⓘ

Study of MDX-010 in Patients With Metastatic Hormone-Refractory Prostate Cancer

ClinicalTrials.gov ID ⓘ NCT00323882

Sponsor ⓘ Bristol-Myers Squibb

Information provided by ⓘ Bristol-Myers Squibb (Responsible Party)

Last Update Posted ⓘ 2014-08-28



Study Details

Researcher View

Results Posted

Record History



Study Record Versions

- This table shows all the versions of this study record arranged in order by submitted date.
- To view one version of the study record, click the submitted date.
- To compare two versions, select them using the check boxes and click "Compare" at the bottom of the list.

	Version	Date submitted (YYYY-MM-DD)	Changes
☐	1	2006-05-08	None (earliest version on record)
☐	2	2006-07-27	- Study Status - Contacts/Locations
☐	3	2006-09-13	- Study Status - Study Description - Eligibility - Study Identification - Conditions - Outcome Measures
☐	4	2006-09-14	- Study Status - Eligibility - Study Description
☐	5	2007-02-27	Study Status
☐	6	2007-06-20	- Study Status - Contacts/Locations - Study Design
☐	7	2008-04-21	- Study Status - Contacts/Locations
☐	8	2008-06-30	- Study Status - Contacts/Locations
☐	9	2008-09-04	- Study Status - Contacts/Locations
☐	10	2008-10-01	- Study Status - Contacts/Locations
☐	11	2009-02-02	- Study Status - Contacts/Locations
☐	12	2009-02-27	- Recruitment Status - Study Status
☐	13	2009-07-22	- Study Status - Study Identification - Oversight - Study Design - Arms and Interventions - Eligibility - Outcome Measures - Study Description - Sponsor/Collaborators
☐	14	2009-10-06	- Recruitment Status - Study Status
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☐	16	2010-01-07	- Study Status - Study Identification
☐	17	2010-01-08	- Study Status - Contacts/Locations
☐	18	2010-04-23	Study Status
☐	19	2011-11-04	- Recruitment Status - Study Status - Sponsor/Collaborators

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			- Study Description - Outcome Measures
☐	20	2011-12-29	Study Status
☐	21	2014-06-24	- Recruitment Status - Study Status
☐	22	2014-08-14	- Study Identification - Study Status - Study Description - Study Design - Outcome Measures - Eligibility - Participant Flow - Baseline Characteristics - Adverse Events - More Information
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Document Section



Version 1: 2006-05-08

Study Details

Study Identification

Unique Protocol ID	MDX010-21
Brief Title	Phase I/II, Open-Label, Dose-Escalation Study of MDX-010 in Patients With Metastatic Hormone-Refractory Prostate Cancer
Official Title	A Phase I/II, Open-Label, Dose-Escalation Study of MDX-010 Administered Every 3 Weeks for 4 Doses in Patients With Metastatic Hormone-Refractory Prostate Cancer
Secondary IDs	

Study Status

Record Verification	2006-05
Overall Status	Recruiting
Study Start	2005-02
Primary Completion	
Study Completion	
First Submitted	2006-05-08
First Submitted that Met QC Criteria	2006-05-08
First Posted	2006-05-10 [Estimated]
Certification/Extension First Submitted	2011-01-29
Last Update Submitted that Met QC Criteria	2006-05-08
Last Update Posted	2006-05-10 [Estimated]

Sponsor/Collaborators

Sponsor	Medarex
Responsible Party	
Collaborators	

Oversight

U.S. FDA-regulated Drug	
U.S. FDA-regulated Device	
Data Monitoring	

Study Description

Brief Summary	This is a multicenter study in which up to 34 patients with metastatic hormone refractory prostate cancer, who have not had previous chemotherapy or immunotherapy treatments will receive MDX-010 every 3 weeks for 4 doses (12 weeks total duration). MDX-010 will be administered at escalating dosage levels of 3, 5, 7.5 and 10mg/kg/dose infusions. At least 6 patients will be enrolled in each dosage level. A total of 16 patients will be enrolled at the maximum tolerated dosage level. Patients will be followed for 1 year or until disease progression. Patients who tolerate and respond to treatment or who have stable disease for 3 months or longer and who subsequently progress during the follow up phase of the study may have the option to receive additional treatment with MDX-010.
Detailed Description	This is a multicenter Phase I/II, open-label, dose-escalation study. Up to 34 chemotherapy- and immunotherapy-naïve patients with metastatic hormone refractory prostate cancer will be administered intravenous (iv) infusions of MDX-010 every 3 weeks for 4 doses at escalating dosage levels of 3, 5, 7.5, and 10mg/kg/dose. At least 6 patients will be enrolled at each dose level. Upon establishment of a maximum tolerated dose (MTD), additional patients, to accrue a total of 16 patients at the MTD dose level, will be enrolled to collect additional data for safety, tolerability, pharmacokinetics, and activity. The duration of treatment for patients is 12 weeks; MDX-010 will be administered on Days 1, 22, 43, and 64. Evaluations to assess clinical response will be performed on Day 85. Patients will then be followed for approximately 1 year or until disease progression. The study duration for each individual patient is up to 16 months. Patients who tolerate or respond to initial therapy with MDX-010 or who have stable disease of 3 months or greater and who subsequently progress during the follow up phase will have the option to enroll in an extension protocol to receive additional cycles of MDX-010 therapy.

Conditions

Condition	Metastatic Hormone-Refractory Prostate Cancer (HRPC)
Keywords	Prostate Cancer Oncology Prostate Cancer Metastatic Hormone PSA

Study Design

Study Type	Interventional
Primary Purpose	Treatment
Study Phase	Phase 1 Phase 2
Interventional Study Model	Single Group Assignment
Masking	None (Open Label)
Allocation	Non-Randomized
Enrollment	34

Arms and Interventions

Arms	Assigned Interventions
	Drug: MDX-010

Outcome Measures

Primary Outcome Measures	1. The primary objectives of the study are to determine the safety profile; 2. maximum tolerated dose (MTD); 3. and dose-limiting toxicity (DLT) of escalating doses of MDX-010 administered every 3 weeks up to 4 times to patients with HRPC.
Secondary Outcome Measures	1. The secondary objective is to provide a preliminary assessment of clinical antitumor activity, including an assessment of PSA responses and metabolic bone activity.

Eligibility

Minimum Age	18 Years
Maximum Age	
Sex	Male
Gender-based Eligibility	
Gender Eligibility Description	
Accepts Healthy Volunteers	No
Criteria	Inclusion Criteria: - signed informed consent form - histologic diagnosis of adenocarcinoma of the prostate - metastatic prostate cancer (positive bone scan or measurable disease) - total testosterone of greater than 50ng/dL, except for patients with prior orchiectomy, where testosterone does not need to be measured. - Patients who are receiving an antiandrogen as part of primary androgen ablation must demonstrate disease progression following discontinuation of antiandrogen and completion of a washout period (specified below), and then observing disease progression: Flutamide must be discontinued at least 4 weeks before beginning screening. Bicalutamide (Casodex), nilutamide, aminoglutethimide, ketoconazole, diethylstilbestrol, megestrol acetate (Megace), and Proscar (finasteride), must be discontinued at least 6 weeks before beginning screening. - Patients must stop using any herbal product known to decrease PSA levels (eg., Saw Palmetto and PC-SPES) or any systemic or topical corticosteroid at least 4 weeks prior to screening. Progressive disease must be documented after discontinuation of these products. - Progressive disease after androgen deprivation (or hormone therapy): For patients with measurable disease, progression will be defined by RECIST criteria. For patients with progression in, or without any measurable disease, a positive bone scan and elevated PSA will be required. - Patients receiving bisphosphate therapy must have been on stable doses for at least 4 weeks with stable symptoms prior to enrollment. - No prior chemotherapy or immunotherapy (tumor vaccine, cytokine, or growth factor given to control prostate cancer). - Prior radiation therapy completed at least 4 weeks prior to enrollment. No prior: radiopharmaceuticals (strontium, samarium) within 8 weeks prior to enrollment. - Life expectancy 12 weeks or greater. - ECOG performance status of 0 or 1. - Patients who are sexually active with a partner who could become pregnant are to use an effective form of barrier contraception. - Must meet screening laboratory values. Exclusion Criteria: - Bone pain due to metastatic bone disease severe enough to require routine narcotic analgesic use. - History of severe hypersensitivity reactions to drugs formulated with polysorbate 80. - Other prior malignancy, except for adequately treated basal or squamous cell skin cancer or superficial bladder cancer, or any other cancer from which the patient has been disease-free for 5 years or greater. - Patients with active autoimmune disease or a history of autoimmune disease that required systemic steroids or immunosuppressive medications, except for patients with vitiligo. - Prior therapy with any anti-CTLA-4 antibody. - Active infection requiring therapy, and positive HIV-1, HIV-2, HTLV-1, hepatitis B surface antigen, or hepatitis C positive RNA. - Underlying medical condition that, in the investigator's opinion, will make the administration of study drug hazardous or obscure the interpretation of adverse events. - Concurrent medical condition requiring the use of systemic or topical corticosteroids, systemic or topical corticosteroids must be discontinued at least 4 weeks prior to enrollment. The use of inhaled corticosteroids is acceptable. - Use of other investigational drugs (drugs not marketed for any indication) within 30 days prior to treatment.

Contacts/Locations

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